

**REMARKS**

Prior to examination of the above-identified application, please amend the application as follows:

**Claim Amendments**

Claims 1-51 are currently pending in the application. Claims 1, 11 and 15 have been amended herein. New claim 52 has been added. Support for the amendment to claims 1, 11 and 15 can be found in the specification as filed, at least at page 2, lines 2-5. Support for new claim 52 can be found in the specification as filed, at least at page 2, lines 2-12 and page 3, lines 1-4. *No new matter has been added.*

**Election/Restriction**

The Examiner has required restriction of the invention under 35 U.S.C. 121 to one of the following groups:

Group I – Claims 1-6, drawn to a method to prevent infections in a subject, classified under Class 514, Subclass 41.

Group II – Claims 7-10, drawn to a method to reduce virulence of a microorganism, classified under Class 514, Subclass 192.

Group III – Claims 11-14, drawn to a method to treat a microbial infection, classified under Class 424, Subclass 93.6.

Group IV – Claims 15 and 17-19, drawn to a method to treat urinary infection, classified under Class 424, Subclass 95.1.

Group V – Claim 16, drawn to a method to treat prostatitis, classified under Class 424, Subclass 114.

Group VI – Claims 20-23, drawn to a method to inhibit virulence in a microbe via administering a compound that inhibits expression of transcription factor, classified under Class 514, Subclass 200.

Group VII – Claims 24-29, drawn to a method to evaluate the effectiveness of a compound to modulate expression or activity of a transcription factor, classified under Class 424, Subclass 9.1.

Group VIII – Claims 30-34, drawn to a method to identify a compound to treat a microbial infection, classified under Class 424, Subclass 94.61.

Group IX – Claims 35-39, drawn to a method to identify a compound to reduce microbial virulence, classified under Class 424, Subclass 404.

Group X – Claims 40-44, drawn to a method to identify transcription factors promoting microbial virulence, classified under Class 424, Subclass 418.

Group XI – Claims 45-49, drawn to a method to reduce the ability of a microbe to reduce [sic] to an abiotic surface, classified under Class 424, Subclass 94.1.

Group XII – Claim 50, drawn to a pharmaceutical composition, classified under Class 435, Subclass 69.2.

Group XIII – Claim 51, drawn to a pharmaceutical composition comprising an antibiotic and a modulation compound for modulating microbial transcription factor, classified under Class 514, Subclass 12.

It is the Examiner's position that the inventions are

unrelated to each other because they are directed to different inventions that are not connected in design, operation/ contents and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group I are directed to a method that will not encompass the same steps or produce the same effect as for example the composition encompassed in Group V invention, and would therefore, may not be practiced together.

Inventions in Groups XII and XIII are related to invention in Groups I-XI as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. In the instant case the method of Group I encompassing Claims 1-6 is applicable to treat any microbial infection in any subject, not just the urinary tract infection. Likewise, said urinary tract infection is treated with a number of over the counter/ other prescription compositions.

Inventions in Groups XII-XII are related to each other as sub-combinations disclosed as usable together in a single combination. The sub-combinations are distinct from each other if they are shown to be separately usable. In the instant case, an invention in

each of Groups XII-XIII has separate utility. For example invention in Group XII is a mixture of a compound that modulates the transcription factor in a microbe and a pharmaceutical carrier and as such application of said mixture to an individual in need thereof will be applicable to treat a microbial infection. The invention ascribed to Group XIII is a composition comprising ingredients of the composition in Group XII invention and additionally comprises an antibiotic, said mixture having the same or similar effect in a subject in need thereof as the mixture of the composition encompassed in claim for invention XII.

Applicants hereby elect ***Group I with traverse***. Applicants traverse the restriction requirement to the extent that Groups I, III, IV and V proposed by the Examiner should be reformed as a single group containing claims 1-6 and 11-19 (referred to hereinafter as "***newly formed Group I***"). Applicants' grounds for traversal are set forth below.

It is respectfully submitted that Applicants have presented an allowable generic claim, new claim 52, which is generic to the claims set forth in groups I, III, IV and V proposed by the Examiner. New claim 52 is drawn to a method for treating or preventing infection of a subject by a microbe comprising administering a compound that modulates the expression or activity of a microbial transcription factor to a subject at risk of developing an infection, wherein said modulation of the microbial transcription factor reduces virulence of the microbe. The claim embodies methods of preventing infection and treating infection as set forth in Groups I and III proposed by the Examiner, as well as treating the specific types of infection set forth in Groups IV and V proposed by the Examiner.

It is Applicants' position that given the presence of claim 52, which is generic to Groups I, III and IV as proposed by the Examiner, a restriction under 35 U.S.C. §121 is improper. In view of the above traversal, Applicants hereby elect ***newly formed Group I***, claims 1-6, 11-19 and 52.

It is Applicants' position that while a species election may be proper among claims 1-6, 11-19 and 52 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim. Claim 52 embraces the species of preventing infections in a subject, treating a microbial infection in a subject, and treating specific types of infection in a subject. If a species election is required, Applicants further provisionally elect the species of preventing a microbial infection in a subject for search purposes only.

It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

**SUMMARY**

If a telephone conversation with Applicant's agent would expedite the prosecution of the above-identified application, the examiner is urged to call applicant's agent at (617) 227-7400.

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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